

REMARKS

A Request for a One (1) Month Extension of Time pursuant to 37 CFR §1.136(a) and (b) is attached hereto.

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action and Advisory Action to which this Amendment is directed. Claims 6, 7, 9, 11, 12, 14-19, 22, 56-59 and 62-66 have been amended in an effort to further clarify and distinctly describe that which is regarded as the present invention. Claims 68-71 have been canceled. To that end, it is believed no new matter has been added.

The Examiner has rejected all pending Claims 2, 6-22, 56-59 and 62-71 on the basis of certain prior art. More specifically, the Examiner has rejected the pending claims under 35 USC §103(a) as being unpatentable over Miller, Muszak et al., or Carey et al., each previously cited by the Examiner, and further in view of Hamilton et al. (U.S. Patent No. 4,568,519). In the later Advisory Action, an additional reference to Jakubowicz (U.S. Patent No. 5,244,633) was noted by the Examiner. Applicants herein respectfully request reconsideration based on the amended claims, as well as the following discussion.

Applicant gratefully acknowledges the interviews granted by Examiner Lyle Alexander to Applicant's representative, Peter J. Bilinski, on December 7 and 14, 2005. The subject matter of this amendment/response includes those discussed during the interview.

Prior to a discussion of the pending prior art rejections, Applicant would again like to refer to the salient features of the present invention. The herein claimed incubator is used in a clinical analyzer and includes a housing having first and second rings that are concentrically situated relative to each other. Each of the inner and outer rings includes respective first and second pluralities of circumferentially disposed sample element receiving areas, these areas being configured and sized for receiving at least one dry slide element. According to the specific embodiment described in the above-captioned application, the inner ring includes a pair of radially adjacent slide element receiving areas while the outer ring includes a single

circumferential array of slide element receiving areas. As such, each of the first and second pluralities of slide element receiving areas are radially adjacent to one another and are further disposed along a common horizontal plane.

The inner and outer rings are each rotatably driven by a first drive mechanism, such as by a belt drive, to enable rotation about their axes, in either a clockwise or counterclockwise direction along the common horizontal plane. Moreover, the inner and outer rings can be driven (e.g., rotated) independently from one another. Each of the rings are provided on the common horizontal plane such that at least one shuttle mechanism, in the form of a reciprocating pusher blade assembly provided adjacent to at least one of the inner or the outer rings of the incubator can be utilized selectively to move slide elements in a radial direction to load and unload elements relative to the incubator housing and also to move at least one slide element between the slide element receiving areas of the outer ring and the inner ring.

More particularly and according to the present invention, the at least one reciprocating pusher blade assembly allows any number of slide elements to be shifted within the confines of the incubator between radially and circumferentially adjacent slide element receiving areas. As such, separately disposed reciprocating pusher blade assemblies that are disposed at discrete circumferential locations relative to the inner and/or outer ring permit any number of slide elements to be selectively shifted between different radial positions in either the inner and outer rings. This selective shifting of slide elements provides unique advantages in that much greater throughput is realized for the clinical analyzer to which the incubator is used, as well as a more efficient means for the scheduling of test events, particularly wherein the outer ring includes at least one instrument for measuring a property of a patient fluid and in which the inner ring includes at least one different instrument for measuring another property of the fluid, each property requiring different protocols (times incubated prior to test) of the incubator.

For example, one reciprocating pusher blade assembly can be used to allocate a slide element that has been loaded into the incubator into one of the slide element receiving areas of the outer ring. The slide element can then be rotated a number of circumferential positions (N) about the axis of the outer ring and then the same or an circumferentially adjacent reciprocating pusher blade assembly can be used to push the slide element into the inner ring, freeing the adjacent slide element receiving area of the outer ring so as to allow the receiving area to load another metered slide element and permitting the shuttled slide element to be moved (e.g., rotated) by the inner ring until the slide element is moved into alignment with a read station. Alternately, other dry slide elements can remain on the exterior or the outer ring, depending, for example, on the type of slide element used and the forms of tests that may be required.

As noted, there are a number of advantages in providing the above features and permitting planar radial and notational movement of incubated elements in the manner herein described. By providing a number of slide elements having different chemistries and having different test protocols, there are also correspondingly different incubation requirements (cycle times). Using the present incubator, a first slide element can be shuttled using a reciprocating pusher blade assembly into the outer ring for potentiometric testing and a second slide element can then be shuttled into the incubator for colorimetric testing upon rotation of the outer ring to a circumferentially adjacent slide element receiving area. Subsequent rotation of the outer ring enables the second slide element to be relocated, such as by the same or another shuttle mechanism, between the radially adjacent slide element receiving area of the outer ring planarly and a corresponding slide element receiving area of the inner ring, while the potentiometric (first) element can remain in the outer ring. In the meantime, additional slide elements can be loaded into the incubator into "freed up" or empty sample receiving areas of the inner ring, effectively increasing throughput. Additionally, an IR wash or other module can be added to the interior of the inner ring, providing further versatility with another radially adjacent reciprocating pusher blade assembly that can be used to planarly move sample

elements into and out of the module and between radially adjacent slide element receiving areas of the inner and outer rings, as the inner and outer rings of the incubator are caused to rotate about their respective axes.

A greater number of slide elements can be loaded into the incubator housing at any one time and handled appropriately wherein the synchronization of the ring/rotor assemblies can be preset, for example, by a predetermined offsetting to permit efficient transfer of slide elements between the concentric rotor assemblies and therefore to efficiently maintain and improve the test schedule of the clinical analyzer.

Turning to the cited art and as previously noted, Miller describes a twin rotor incubator assembly for a clinical analyzer. The incubator assembly that is described includes a pair of independently driven, vertically stacked rotors 52, 54 that are interconnected by means of an elevator assembly relative to a metering station. The rotors are not provided on a common horizontal plane. As slide elements are metered, the elements are brought into either of the vertically stacked rotors using a pusher blade. In order to move any of the sample elements between these stacked and offset rings, however, there must be a vertical component of movement in order to access the remaining rotor. That is and in order to move sample elements between the vertically stacked ring elements in order to “free up” space, for example in one of the rings, the slide element must first be removed from one of the rings, loaded onto the elevator assembly, raised or lowered, and then reloaded horizontally into the remaining ring. That is to say, the sample element receiving areas of the first and second rotors are not provided on a common horizontal plane and therefore movement of slide elements between the slide element receiving areas of the rotors does not occur exclusively along a common horizontal plane. Because this reference fails to disclose a relationship between first and second pluralities of slide element receiving areas that would permit radial movement therebetween, it is not understood how this reference can anticipate the present invention.

Muszak et al. teaches the elevator assembly that is used by the incubator that is described by Miller. As such, this reference elevator fails to provide or suggest any structure or a resulting mechanism that is capable of radial transport strictly along a common horizontal plane between radially adjacent slide element receiving areas that are disposed on coplanarly arranged inner and outer rings.

Carey et al. describes an incubator assembly that is used to handle multiple assays in an immunoassay clinical analyzer. The incubator includes a housing having a single cuvette ring that includes a plurality of circumferential slots, each sized for receiving a cuvette. The cuvette ring is disposed above a magnet ring used in conjunction with a drive assembly 18 to drive the cuvette ring. The cuvette ring is driven radially so as to pass a plurality of circumferentially arranged stations, including read stations. In addition, a number of other circumferentially disposed stations are positioned outside of the incubator housing as used to dispense reagents, wash fluids, and perform other assay reaction steps. The cuvettes are not moved to positions other than the cuvette ring during any read, aspirate or dispense operation utilizing the exterior disposed stations. This incubator also includes an elevator assembly, as described at col. 18, lines 56-67, wherein a cuvette can be lifted from a slot to permit a new cuvette to be added to take a now empty slot in the cuvette ring. To that end, this reference is significantly different structurally from the claimed invention in that this reference fails to describe radially adjacent rings having slide element receiving areas wherein movement can be achieved between the rings along a horizontal plane.

The secondary reference to Hamilton et al. describes a slide distributor for the delivery and removal of slide elements from an incubator. See col. 1, lines 9-11. The slide distributor is defined by a single shuttle mechanism that is located outside of the incubator housing that can be used to either load or unload slide elements from an incubator. The advantage that is sought according to this reference is that a slide element can be unloaded and a new slide element can be loaded into the incubator in a relatively short period of time (see col. 2, lines 1-9), facilitating the

time that tests can be conducted in the incubator. The shuttle mechanism includes a single pusher blade having a picker to enable the slide elements to be loaded and/or unloaded from the single ring incubator.

Applicant does not claim to have invented a shuttle mechanism for loading and unloading slide elements from an incubator. To that end, Applicant acknowledges that Hamilton teaches a single shuttle blade design that is used in conjunction with a single rotor incubator. In that sense, such mechanisms are also similarly described by Miller and Muszak et al., previously cited herein. Details relating to the single ring incubator in Hamilton, according to this reference, are disclosed in U.S. Patent 4,296,069 to Smith et al, a copy of the Smith '069 patent being attached hereto for the Examiner's reference.

The Smith incubator is defined by a single rotor mounted within a housing and includes a single plurality of slide holders 24 wherein slides are loaded from a single station according to a predetermined protocol, as the single rotor rotates. On the other hand, Applicant has devised a twin horizontal ring design that can utilize at least one reciprocating pusher blade assembly or a plurality of such assemblies to radially shuttle slide elements either into a first plurality of slide element receiving areas, into a second plurality of slide element receiving areas and/or between the first and the second slide element receiving areas of the rings along a common horizontal plane. All movement, whether into, out of, or throughout the incubator is done planarly.

Newly cited Jakubowicz '633 recites an incubator structure wherein a series of cup-shaped cuvettes are disposed in plurality of element receiving areas between a pair of adjacent rings. The incubator further includes a push/pull rod mechanism that permits movement between various locations on the rings. The '633 reference does not utilize slide elements, but rather utilizes a series of cup-like reaction vessels or cuvettes that are placed in each of a plurality of receiving areas of each of the inner and outer rings. The cuvettes are initially loaded into the outer ring by some form of device (not shown or described) that vertically loads or drops the cuvettes

into an appropriate receiving area. To that end, the cuvettes are not radially loaded into the inner ring of the incubator nor is any device shown or suggested that is capable of such a function.

The mechanism, see Fig. 14, that is used to move the cuvettes between the outer ring and the inner ring is described at col. 6, line 59 – col. 7, line 27 of Jakubowicz '633 is referred to as transfer means 200 comprising a push rod 202, 204. As described in the reference, each of the rods are used for a specific aspect of transfer wherein rod 202 is used to effectuate transfer between the outer ring and the inner ring and the remaining rod 204 is used to effectuate transfer from the inner ring to a dump station (not shown). Each rod 202, 204 includes a terminal lip 206 that is disposed sufficiently to engage the interior of a cuvette and wherein each rod is pulled toward axis 55. See Figs. 14-16. As such, a two part operation is necessary to effectuate transfer using each of the two rods. The present apparatus uses a pusher blade assembly that includes a pusher blade capable of moving a slide element not only between the rings of the incubator, but also into and out of the incubator itself.

It would not be obvious to include Jakubowicz with a reciprocating pusher blade assembly since this reference does not in any way relate to the use of slide elements given the cup-shaped design of the cuvettes.

Claims 62, 63 have now been amended to specifically indicate that each of the sample elements used in connection with the present incubator are slide elements. In addition, these claims have also been amended to specify that the second drive mechanism comprises at least one reciprocating pusher blade assembly that enables radial movement either into and/or out of the incubator, as well as radial movement between the inner and outer rings. Support is found repletely in the present application and drawings and therefore it is believed that no new matter has been added.

It is believed that none of the prior art cited by the Examiner provides the structure as now claimed. Though the cited art of Miller, Muszak and Hamilton each include a shuttle mechanism for moving a slide element into a single rotor incubator, there is no description or suggestion in any of the prior art in which at least one reciprocating pusher blade assembly is used in conjunction with a horizontal twin rotor design to effectuate throughput, according to the present invention. That is, none of the prior art, either singly or in combination, describes or suggests a twin rotor structure as presently claimed by Applicant wherein at least one reciprocating pusher blade assembly can be used to selectively shuttle a slide element into the incubator and also between each of the radially adjacent slide element receiving areas of the inner and outer rings. Each of Carey and Jakubowicz '633, do not even relate to the transfer of slide elements, as each of these cited references relate to incubators using cuvettes requiring an entirely different form of transfer mechanism.

To that end, it is believed that a "*prima facie*" obviousness rejection cannot be maintained based on the cited art. The combination of the cited art fails to provide the structure of the invention that is now positively recited in independent Claim 62. That is, none of the cited prior art, either singly or in combination, provides an incubator having an inner and an outer ring wherein the inner ring includes a first plurality of circumferentially disposed slide element receiving areas and the inner ring includes a second plurality of slide element receiving areas. As previously noted, each of the primary references to Muszak et al. and Miller define first and second pluralities of slide element receiving areas, but in which the areas are not radially adjacent or at least in which movement cannot occur between the areas along a horizontal plane common to the slide element receiving areas. Hamilton refers to a single rotor incubator design while Carey and Jakubowicz '633 each describe incubators that transfer cuvettes and not slide elements.

Moreover, none of the cited art alone or in combination, recites or suggests at least one reciprocating pusher blade assembly that selectively moves slide elements exclusively in a radial direction along the horizontal plane common to the first and second plurality of slide element receiving areas, as well as in relation to apparatus disposed outside the incubator housing. Since Miller and Muszak et al. specifically require the rings be vertically stacked, the sample element receiving areas cannot be formed within a common horizontal plane as required by each of independent Claims 62 and 63. Carey and Hamilton each relate to single ring structures only and Jakubowicz '633 describes an incubator that is evidenced by other than a reciprocating pusher blade assembly to achieve movement. Moreover and as previously noted, each of Carey and Jakubowicz do not relate at all to the transfer of slide elements, but rather to cuvettes, which cannot be operated upon via reciprocating pusher blade assemblies. As previously noted, the cuvettes of the instant references cannot be loaded radially into the outer ring according to either reference and it is surmised that the cuvettes must be loaded vertically. For the foregoing reasons, it is believed that a prima facie obviousness rejection cannot be made regarding Claim 62.

Each of Claims 3, 6-22, 56-59, and 64-67 are believed allowable since these claims depend from Claim 62. Reconsideration is respectfully requested.

Independent Claim 63, as amended, recites a method of incubating and reading test slide elements using a sequential random incubator in a clinical analyzer, wherein the analyzer includes an inner ring and an outer ring, the outer ring having a first plurality of circumferentially disposed slide element receiving areas and the inner ring having a second plurality of circumferentially disposed slide element receiving areas in which each of the first and second pluralities are radially adjacent to one another on a common horizontal plane. As previously noted, none of the cited prior art recites or suggests this specific structure. The method steps further distinguish in that the steps that are recited include radially loading at least one slide element into an empty slide element receiving area as well as movement rotationally of at least one of the inner and outer rings along the horizontal plane. The claimed

method requires the radial movement of at least one slide element between the first and second pluralities of slide element receiving areas along the common horizontal plane. This latter step is not remotely suggested or taught in any of the cited prior art since none of this prior art has the supporting structure to perform that movement. As previously noted, each of Miller and Muszak et al. clearly require that movement between slide element receiving areas of the twin rotors MUST occur by vertical movement via an elevator assembly between the two vertically stacked rotors. Hamilton et al also teaches movement in a single rotor assembly and therefore only relative to one plurality of circumferentially disposed sample element receiving areas. Carey et al. and Jakubowicz '633 each clearly require some form of vertical and not radial loading of cuvettes used in each of the incubators described therein, as opposed to slide elements. Moreover, Carey relates to a single ring design and Jakubowicz '633 includes a push/pull rod mechanism that requires two components to effectuate transfer between rings and then from the rings out of the incubator. As such, this reference fails to describe or suggest use of a reciprocating pusher blade assembly that enables horizontal movement to enable loading of at least one slide element into the incubator and then to permit reciprocating movement between the inner and outer rings. As a result, we believe features recited in Claim 63 are entirely missing from this cited art, these features not being found or suggested either singly or in combination, absent hindsight. Therefore, it is believed that a "*prima facie*" case of obviousness cannot be maintained with regard to this claim and this rejection should therefore be withdrawn.

Claims 6, 7, 9, 11, 12, 14-19, 22, 56-59 and 64-66 have been amended to comport with the amended language of Claims 62 and 63. To that end, it is believed no new matter has been added.

Claims 68-71 have been canceled. The rejections with regard to these claims are therefore moot.

Serial No.: 09/904,692

Amendment Dated: February 6, 2006

Reply to Office Action of October 5, 2005 and the Advisory Action of January 18, 2006

In summary, it is believed the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

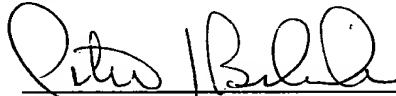
If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicants' representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

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